European Food Safety Authority

Pertinent studies for substantiation
Gut and immune function as an example

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If a food/constituent is not sufficiently characterized, a cause and effect relationship between the food/constituent and the effect cannot be established

If the claim is for a constituent, studies to substantiate the claim need to be presented on that constituent

If the claim is on a specific product formulation/combination of constituents, studies need to be presented on this formulation

A rationale for the role of each constituent relevant to the claimed effect should be provided

- Gastrointestinal function/comfort
  - Defense/immune system

Gastrointestinal function/comfort

- Function
  - Regularity
    - Measures of transit time
    - Number of stools
  - Measures of bulking
- Comfort
  - Measures of discomfort
  - Bloating

- Microbiota
  - What constitutes a health microbiota
  - Good bacteria?

- Merely enhancing bifidobacterial numbers is not a health benefit as itself (FAO, ILSI, EFSA)

Possible measures

- Immune system: What does improvement of immune responses mean?
  - IgA
  - NK
  - Phagocytes
  - IgE
  - Interleukins
  - Markers of inflammation
  - Reducing pathogens
  - Reducing incidence of infections

Reducing pathogens

- Function
- Risk factor

Food borne pathogens Reduction is beneficial

- *Salmonella*
- *Campylobacter*
- *Listeria*
- *Yerssinia*
- *Shigella*
- *S aureus*
- *C botulinum*
- *B cereus*
- *V vulnifuncus*
- Norovirusses
- *Echinococcus*
- *Toxoplasma*
- *Giardia*

Oro-gastrointestinal pathogens Reduction is beneficial

- *S mutans*
- *S sobrinus*
- *H pylori*
- *C difficile*
- *C tetani*

Need for characterization as pathogenic

- *C perfringens*
- *E coli*

Study design

- Longitudinal study: reduction in same individuals
- Multiple time points
- Statistical significant differences
- Clinical outcome?
- At least one log difference?
- More than one study?